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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,732	07/20/2000	GEORGES SMITS	TIENSE RAFF.	8993

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HAYES, SOLOWAY P.C.
130 W. CUSHING STREET
TUCSON, AZ 85701

EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,732	SMITS ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-70 and 72-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-70 and 72-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.o.c

DETAILED ACTION

Status

1. The current application was returned by the BPAI after reversal decision. The decision indicated that the examiner offers no evidence to support for optimization conditions of the conventional chicory inulin growing process and no evidentiary support to show that the prior art, Van den Ende et al., performed the study during the time period at which the temperatures never dropped below minus 1^0 C in Heverlee, Belgium. Accordingly the Board reversed the rejection of claims 65-70, 72-97 under 35 USC 103(a). To address the issue of the temperature, the Examiner herewith provides meteorological data from The Royal Institute of Meteorological Center, Belgium for the year 1994, during which time Van Den Ende et al. performed their study. Accordingly, the Examiner reopens the prosecution.

2. Claims 65-70, 72-97 are pending in this application and are considered for examination in this office action.

3. This application filed on July 20, 2000 is a 371 of PCT/EP99/00155 filed on 1/13/199, which claims benefit of foreign priority EPO 98870012.6 filed on 1/13/1998.

Requirement for Information

4. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

Several pieces of information are relevant to the examination of this application. First, does Applicant have separate temperature information for Heverlee, Belgium, for the period of June 1, 1994 to December 9, 1994. Second, does Applicant have evidence regarding triggering

of the fructan exohydrolase gene by low temperature during the growth period of Van den Ende. That is, was the temperature low enough to trigger this gene or not? Third, did the temperature during Van den Ende's growth conditions ever drop below –1 degree Celsius? Fourth, is Applicant aware of the longest period of cultivation of the chicory by Van den Ende? It appears to be 189 days, is this correct?

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claim 65-70, 72-78, and 89-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (USPN. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996) and (Institut Royal Meteorologique de Belgique, temperatures for January 1, through December 31, 1994).

Yamazaki et al. teach a method as in claim 65, for improvement of processing of chicory inulin from chicory roots through conventional manufacturing techniques, wherein Yamazaki et al. disclose that the source material for the process are tubers of Jerusalem artichoke (see column 11, lines 62-66); grown in appropriate regions under proper climatological temperature (grows well in colder conditions, even in waste lands) (see column 12, lines 3-9).

With regard to claim 66-70, Yamazaki et al. also discloses that the inulin could also be derived in similar fashion and could be efficiently produced and harvested in late October and ideally should be processed within a few months (see column 12, lines 21-27);

With regard to claims 73-78, Yamazaki et al. disclose improvement obtaining partial or substantially complete hydrolysis product of inulin (see column 11, lines 62-66); the method of extracting inulin (40%-70% by weight) further comprises extraction with hot water and refining inulin by filtering and cation-exchange (see column 11, lines 1-49);

With regard to claims 89-97, Yamazaki et al. disclose production of fructo-oligosaccharides from inulin (see column 10, lines 36-56); fructooligosaccharides containing about 0-100% by weight of monosaccharides (see column 10, lines 51-56).

However, Yamazaki did not teach the periods of seeding/growing/processing under climatological temperature conditions, wherein the growing period in northern hemisphere selected from the periods ranging from December 1 till March 14, from March 15 till May 14, from May 15 till May 31, from June 1 till June 14, and from June 15 till November 30, provided that when said chicory has been seeded in the periods from May 15 till May 31, and from June 1 till June 14, the chicory roots have had a growing period of at least 180 days, and provided that when said chicory has been seeded in the period from March 15 till May 14, and in southern hemisphere within a period selected from the periods ranging from June 1 till September 14, from September 15 till September 30, from October 1 till November 14, from November 15 till November 30, and from December 1 till May 31, which are such that during a period of at least from the beginning of the third month of the growing period till the end of the processing of the chicory roots the fructan exohydrolase (FEH) gene in chicory roots, has not been triggered by the occurrence of low temperature conditions which are such that the temperature in a thermometer shelter not have dropped below minus 1^0 C.

Van Den Ende et al. teach a process of claims 65-70, 72-78, 89-97, for synthesizing fructan (inulin) from chicory roots wherein Van Den Ende et al. disclose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, July 26th to November 3rd , October 4th to October 25th, September 13th to December 6th (the period from June 1st to December 6th is 189 days, which is more than 180 days, see page 44, column 1, paragraph 4) ; (iii) chicory roots stored at +1^{0} C and analyzed at regular intervals (at least once a week) (see page 44, column 1, paragraphs 1 and 4) and (iii) inulin was obtained with a standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (page 45, column 1, paragraph 3). Van Den Ende et al. also disclose changes in the activities of FET during growth, storage and forcing and suggests that cold storage results in a rapid depolymerization of large fructans with a simultaneous increase in smaller fructans, sucrose and fructose (see page 47, col. 1, paragraph 2, page 48, col. 2, paragraph 4).

Further the meteorological data from the Royal Institute of Meteorological center, Belgium provides support for the temperatures during March 1, 1994 through December 31, 1994, which indicates that the temperatures never dropped below minus 1^{0} C, except for two days in December, 1994 (see the chart for temperatures for 1994, wherein December 15 and 16 of 1994 had temperatures below minus 1^{0} C, these two days are out of the growing and processing period of Van Den Ende et al., wherein their growing and processing period ended on December 6th, 1994).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify the process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the optimization of the process of growing and harvesting chicory roots as taught by Van Den Ende et al. and the temperature conditions disclosed by the Royal Institute of Meteorological center, Belgium to achieve expected advantage of developing an improved process for manufacturing chicory inulin from chicory roots under proper climatological temperatures because Van Den Ende et al. states that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). Van Den Ende et al. also taught changes in the activities of FET during growth, storage and forcing and suggests that cold storage results in a rapid depolymerization of large fructans with a simultaneous increase in smaller fructans, sucrose and fructose (see page 47, col. 1, paragraph 2, page 48, col. 2, paragraph 4). Therefore the effect of low temperatures on inulin degradation is a limiting parameter, which is obvious, and known from the prior art cited. Further the meteorological data shows that the temperatures never were below minus 1^0 C except for two days in December, 1994). An ordinary practitioner would have reasonable expectation that the combination the method of Yamazaki et al. by incorporating the proper climatological conditions, (that is avoiding no frost days) which partially or wholly fall outside conventional seeding and growing conditions taught by Van Den

Ende et al. and the Royal Institute of Meteorological data center, would result in achieving the expected advantage of developing an improved process of preparing chicory inulin. Thus the effect of limiting parameter (low or frost temperatures on FET activity) is known at the time the invention was made and it is prima facie obvious to avoid such conditions in the cultivation of chicory roots. Thus it is prima facie obvious to optimize the cultivating conditions not to fall in the low temperature conditions, and such modification of the method is considered obvious in the absence of secondary considerations.

B. Claims 79-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (USPN. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996) and The Royal Institute of Meteorological Center, Belgium, 1994 as applied to claims 65-78, 89-97 above, and further in view of Van Loo (USPN. 5,660,872).

Yamazaki et al. teach a method for processing of chicory inulin from chicory roots through conventional manufacturing techniques, wherein Yamazaki et al. disclose that the source material for the process are tubers of Jerusalem artichoke (see column 11, lines 62-66); grown in appropriate regions under proper climatological temperature (grows well in colder conditions, even in waste lands) (see column 12, lines 3-9). Yamazaki et al. also discloses that the inulin could also be derived in similar fashion and could be efficiently produced and harvested in late October and ideally should be processed within a few months (see column 12, lines 21-27); obtaining partial or substantially complete hydrolysis product of inulin (see column 11, lines 62-66); the method of extracting inulin (40%-70% by weight) further comprises extraction with hot water and refining inulin by filtering and cation-exchange (see column 11, lines 1-49); production of fructo-oligosaccharides from inulin (see column 10, lines 36-56);

fructooligosaccharides containing about 0-100% by weight of mono saccharides(see column 10, lines 51-56).

Van Den Ende et al. teach a process for synthesizing fructan (inulin) from chicory roots wherein Van Den Ende et al. disclose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, July 26th to November 3rd , October 4th to October 25th, September 13th to December 6th (see page 44, column 1, paragraph 4) ; (iii) chicory roots stored at $+1^{0}$ C and analyzed at regular intervals (at least once a week) (see page 44, column 1, paragraph 4) and (iii) inulin was obtained with a standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (page 45, column 1, paragraphs 1-4).

However, neither Yamazaki et al. nor Van Den Ende et al. teach the production of inulin free of monomeric saccharides, dimeric saccharides and oligofructose.

Van Loo et al. teach a method for producing inulin free with low molecular weight polysaccharides (sugars) wherein Van Loo et al. disclose that the method comprises isolation of inulin from chicory roots with hot water to obtain aqueous solution of inulin, purification of inulin followed by concentrating the inulin solution by partial removal of water (see column 11, lines 47-62); the method also comprises obtaining inulin free of mono-and disaccharides, drying inulin to a particulate form (see column 12, lines 1-67, column 13, lines 1-17). Van Loo et al.

further discloses obtaining inulin free of low molecular weight polysaccharides with DP greater than 5 (column 5, lines 5-44).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the method of growing and harvesting chicory roots as taught by Van Den Ende et al. and the method of producing polydispersed saccharides as taught by Van Loo et al. to achieve expected advantage of developing a process for manufacturing improved Grade chicory inulin from chicory roots under proper climatological temperatures and because Van Den Ende et al. taught that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). Further, Van Loo et al. taught that "the degree of polymerization (DP) has direct effect on the solubility of inulin and varies according to the conditions of harvesting chicory roots and saccharides comprise a DP greater than 2 would result in coloration, difficulty in solubility and crystallize at temperatures below 65^0 C" (see column 1, lines 55-67, column 2, lines 1-22). An ordinary practitioner would have been motivated to modify the method of Yamazaki et al. by incorporating the proper climatological conditions and production of inulin free of polydispersed saccharides as taught by Van Den Ende et al. and Royal Meteorological data center and further

in view of Loo et al. in order to achieve the expected advantage of developing a method for production of improved grade inulin.

Response to BPAI decision

6. The BPAI decision is fully reviewed but in the light of new evidence this action is reopened. The BPAI decision to reverse the prima facie obviousness rejection over claims 65-70 and 72-97 are based on the following arguments:

The BPAI argues that there is no evidence that the temperature did not drop below minus 1°C in Heverlee, Belgium despite the fact that the examiner provided evidence regarding the temperatures in Brussels, Belgium. The new evidence of record, the meteorological data from the Royal Institute of Meteorological Center, Belgium, shows the daily temperatures for the year 1994, during which time Van Den Ende (the prior art of the record) performed their study. Heverlee, Belgium is 15 minutes by car from Brussels International Airport. Essentially Heverlee is a suburb of Brussels. In the Appeal Brief, Applicant noted that Heverlee is 14 kilometers from Brussels. No separate information was available for Heverlee in 1994.

The BPAI stated "In addition, we note that the growing period from June 1, 1994 through October 15, 1994 is 136 days, which is less than the growing period "of at least 180 days" for plants seeded on June 1 as required by appellants' claimed invention. (see page 7 of BPAI decision). This statement is factually incorrect. While the BPAI is correct that the plants were seeded on June 1, 1994, Van Den Ende expressly teaches harvesting as late as December 6th. As Van Den Ende notes, "On a weekly basis, nine plants were uprooted (to investigate fructan synthesizing (July 26th - November 3rd) and/or fructan degrading (September 13 - December 6)

activities (see page 44, subheading "Plant material"))". The period from June 1st to December 6th is 189 days, which is more than 180 days and meets this element of the claim.

The BPAI stated "The examiner, however, fails to identify the evidence in Van Den Ende that fructan exohydroxylase has not been triggered. (see page 6 of BPAI decision)" . The claim does not state the Fructan exohydrolase is not triggered at all, but rather, the claim is addressed to the conditions under which fructan exohydrolase is not triggered. The claim states "the fructan exohydrolase (FEH) gene in the chicory roots has not been triggered by the occurrence of low temperature conditions which are such that the temperature in a thermometer shelter shall not have dropped below minus 1°C (see claim 65, lines 6-9)."

The issue is not whether Fructan exohydrolase is triggered at all, but whether it is triggered by the occurrence of low temperature conditions. Consequently, when the BPAI points to Van Den Ende as showing expression of fructan exohydrolase, this is not relevant to the invention as claimed. The BPAI's entire discussion on pages 8 and 9 is not germane to the claim because the issue is not whether fructan exohydrolase is triggered in Van Den Ende by anything, but whether fructan exohydrolase is triggered by low temperature conditions. It is for this reason that evidence was presented that no such conditions were present.

The BPAI concludes, "In affirming the rejection in In Re Cruciferous Sprout Litigation, the Court found the prior art of record inherently contains the limitations set forth in the claim. Contrary to the issue in In Re Cruciferous Sprout Litigation, the issue before us on this appeal is whether the claimed invention is obvious under 35 U.S.C. 103. (see page 11 of response)." The CAFC did not limit the In Re Cruciferous Sprout Litigation to 102 situations, but expressly indicated that where an element, in that case the expression of an enzyme activity in broccoli

sprouts, was unknown, but the elements were otherwise the same, then the product must be identical. The In Re Cruciferous Sprout Litigation is precisely on point in this case, because the only difference between the claims and the standard growth methods of chicory is that low temperature does not trigger Fructan exohydrolase. The issue is as nearly identical as possible. In Re Cruciferous Sprout Litigation mandates that where every element that can be determined is identical, then the properties will be presumed identical.

As the CAFC noted "The prior art indisputably includes growing, harvesting and eating particular sprouts which Brassica has recognized as being rich in glucosinolates and high in Phase 2 enzyme-inducing potential. But the glucosinolate content and Phase 2 enzyme-inducing potential of these sprouts are inherent properties of the sprouts put there by nature, not by Brassica. Brassica simply has not claimed anything that is new and its claims are therefore invalid." This is precisely the same situation, though in a 103 context. The prior art includes growing, harvesting and processing chicory roots to obtain chicory inulin. The temperature dependence of the enzyme was not known, but this is a necessary and inherent property of chicory grown under the claimed conditions. So there is nothing new and the claims are prima facie obvious.

Accordingly, upon reconsideration of the BPAI decision and evidentiary support from The Royal Meteorological Center, Belgium, the Examiner reopens the prosecution.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Examiner
Art Unit 1637

JEFFREY FREDMAN
PRIMARY EXAMINER
5/17/05

Jasemine C. Chambers

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600